CHAPTER 4

FROM MICROBES TO XENOTRANSPPLANTS: ANALYZING THE BIO-PATENTING CONUNDRUMS

In the foregoing chapter, eligibility and grant yardsticks were analysed by researcher. Here and in the next chapter, we see how the same are evolved and applied in context of certain bio-innovations. We begin with study of GM microorganisms. From there, we engage with other transgenic organisms, including human beings and human clones and xenotransplants. Other areas are dealt in our next chapter, where we cover, *inter-alia*, stem cells and human genetic research. Our analysis here will enable us to gauge the kind of multitudinous oppositions, the fears, the policy concerns, the arguments, and also the bewildering science related to bio-patents, and also how different jurisdictions responded thereto. It is bewildering indeed that all of it started with the humble microbes, which laid the foundation, from where, as if on the proverbial “slippery slope”, patents, almost unabatedly, embraced *hitherto* unimaginable, incredibly complicated, and increasingly controversial innovations. We must mention that, henceforth, all references to all organisms would imply GMOs or transgenic organisms, since natural organisms, simply cannot be monopolised or patented.

4.1. MICROORGANISM PATENTS, VACCINES & ANTIBIOTICS

We begin with our focus on microbes. The most important judgment came, in context thereof, from U.S. It is recognized as a watershed, a landmark in bio-patent jurisprudence. Although currently microorganisms are universally patentable yet an in-depth analysis of the afore-mentioned judgment serves well since the arguments or
perspectives, the spectrum of conflicting claims encountered therein formed the bedrock of most future arguments in this field. But firstly, we engage with definitions.

**Microorganisms, Definitional Issues & Uses:** Interestingly, no treaty or law engaging or dealing with microorganism-patents defines them. The dictionary definition is that, “an organism of microscopic or less that microscopic size” is a “microorganism”\(^1\). Hence, all “bacteria, viruses, viriods, eukaryotic single cell and multi-cellular microorganisms like yeast, protozoa, fungi, moulds and algae” are so classified\(^2\). Also, within patent law, “cultured plant and animal cells” are so classified\(^3\). It can also mean “only unicellular organisms” which would then exclude “cell lines, genes and gene sequences”\(^4\). However, such “cell lines, genes and gene sequences” are also, as our next chapter shows, patentable, if non-natural. As regards their use, these are, as our chapter 2 showed, integral to fermentation. They are employed also in producing industrial chemicals like “acetic acid and acetone”\(^5\). In antibiotics’ manufacture as well, there is reliance “upon the isolation of products from selected strains of microorganisms”\(^6\), and despite synthetic production, many antibiotics “are still made from microorganisms, either found in nature or artificially mutated”\(^7\). It is said that,

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\(^1\) Webster’s “New Encyclopedic Dictionary” (New York, 1995)

\(^2\) S.K. Chaudhri, “Microbial Biopiracy in India: How to Fight Back?” 8 *JIPR* 389-399 (Sep., 2003), 390

\(^3\) *Ibid.*

\(^4\) J. Watal, *Intellectual Property Rights in the WTO and Developing Countries* 132 (OUP, N. Delhi, 6\(^{th}\) Imp., 2014)


\(^6\) *Ibid.*

\(^7\) *Ibid.*
“In the medical field, microorganisms are used to produce a host of life-saving therapies- antibiotics, vaccines, insulin - and - diagnostic tools.”

Hence, microbes are useful. Their usefulness or desired traits could be enhanced or tweaked using, inter-alia, rDNA technique. Question is: Could the tweaked microbes be patented?

4.1.1. THE FIRST PATENTS: PASTEUR’S YEAST TO CHAKRABARTY’S BACTERIA

Contrary to popular beliefs, Louis Pasteur, in 1873, got the first patent for “Improvement in the manufacture of Beer and Yeast” in U.S.9. It claimed, inter-alia, “The method of obtaining pure yeast by eliminating the organic germs of disease from brewer’s yeast, in the manner described” and also “yeast, free from organic germs of disease, as an article of manufacture”10. It is labelled as “an early case of a patent for living organisms”11. But then USPTO, for unexplained reasons, never allowed such applications again, until 1980. Consequently, one author noted that, “pharmaceutical firms that used microbial strains to produce antibiotics had typically sought patent protection on methods” and never “on the strains themselves” i.e. the products12. However, in 1972, i.e., a century later, Ananda Chakrabarty applied for “Microorganisms having multiple compatible degradative energy-generating plasmids”13. It covered, inter-alia, the “living bacteria”. Such application, in those

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8 Catherine Jewell, “WIPO’s Budapest Treaty facilitates biotech patenting” 4 WIPOMag. 2-7 (Aug., 2015), 4
9 U.S. Patent No. “141072”
10 Ibid.
11 Supra 5
13 U.S. Patent No. “4259444”
nascent days of genetic engineering, was unusual. Unsurprisingly, USPTO rejected product claims, holding that, firstly, “microorganisms are products of nature” and, secondly, being life-forms, “they are not patentable subject matter”\textsuperscript{14}. After traversing appellate forums, ultimately, the “bacterium dispute” reached Supreme Court\textsuperscript{15}.

4.1.2. \textit{CHAKRABARTY AT THE SUPREME COURT}

Interestingly, around that time, public perception of biotech techniques was changing. As Eisenberg commented, “commercial potential of biotechnology had become manifest” which led to “a host of amicus curiae briefs from the scientific community” being filed in Chakrabarty’s favour\textsuperscript{16}. Hence, a more accepting, positive climate was emerging. However, those against it, argued on “evolutionary, ethical, philosophical” basis for objecting to “patenting of living organisms” and, moreover, they also expressed fear that it will “lead to patenting of higher life forms”\textsuperscript{17}. This fear, as shown herein, ultimately did turn true. In this background, U.S.S.C. narrowed everything to a simple question, “whether a live, human-made microorganism is patentable subject matter”\textsuperscript{18}. The slim 5:4 majority, said, “Yes”. Its rationale, for ease of analysis, is summarized now.

\textbf{Interpreting the Statue}: The majority opined, endorsing its earlier rulings, that “manufacture” implied “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or

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Interestingly, 35 U.S.C. § 101 says that “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title”.
\textsuperscript{15} Initially, “Chakrabarty appealed the rejection” ... “to the Patent Office Board of Appeals” which sided with USPTO, but on next appeal, “Court of Customs and Patent Appeals, by a divided vote” held in favour of Chakrabarty. From there, it reached U.S.S.C. For this chronology and facts, see, \textit{id}. at 306-307
\textsuperscript{16} \textit{Supra} 12 at 318
\textsuperscript{17} Matthew Rimmer, \textit{Intellectual Property and Biotechnology: Biological Inventions} 33-34 (Edward Elgar, Cheltenham, 2008)
\textsuperscript{18} \textit{Supra} 14 at 305
\end{flushleft}
combinations, whether by hand-labour or by machinery” 19. Further, it said that, “composition of matter” implied “all compositions of two or more substances and all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids” 20. So construed, the Court observed, these phrases imparted “wide scope” to patent laws 21. Therefore, it held, that, Chakrabarty’s “claim” extended “to a nonnaturally occurring manufacture or composition of matter, a product of human ingenuity” 22.

The Legislative Intent: Relying, inter-alia, on Jefferson, whose philosophy, that, “ingenuity should receive a liberal encouragement” guided U.S. patent jurisprudence 23, the majority deduced that,

“The Congress intended statutory subject matter to include anything under the Sun that is made by man.” 24

This became the credo, the foundation stone of bio-patents in U.S.

The “Made by man” Argument: The majority opined that, “the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility” 25. It noted further that Chakrabarty’s work is “not nature’s handiwork, but his own” 26. The majority also stated that,

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19 Id. at 308
20 Ibid.
21 Ibid.
22 Id. at 309
23 Id. at 308
24 Id. at 309
25 Id. at 310
26 Ibid.
“The relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions”.

The “Anti-Patent” Arguments: The majority just brushed aside the argument that “micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection”. In response to corollary arguments that, “genetic research may pose threat to the human race” and further that such research “may spread pollution and disease” and, consequently, “depreciate the value of human life”, the majority merely opined that, “we are without competence to entertain these arguments” and “the choice” involved “matter of high policy” which is task of Congress/legislature. Curiously, even though majority admitted it was “without competence” to balance all arguments, yet it went ahead, without inhibitions, to increase patent law’s ambit forever. Further, it added that,

“The grant or denial of patent on microorganisms is not likely to put an end to genetic research or to its attendant risks” ... “legislative or judicial fiats as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.”

To admit that “grant or denial of patent” would “not likely” thwart “genetic research” exposes the tall claim that “patents promote innovation”. Nevertheless, the bacterium was monopolised and, as we noted above, it paved the way for many other so-called “bio-patents”.

27 Id. at 313
28 Id. at 314
29 Id. at 316
30 Id. at 317
31 Ibid.
4.1.3. MICROORGANISMS & INDIAN SCENARIO

Today, obviously due to TRIPS (discussed in next segment), in India, “microorganisms” are considered “inventions”\(^{32}\). Unlike U.S., therefore, where, in this context, extended judicial debate was held, India simply followed the TRIPS diktat. However, one matter stands out. Before the final “TRIPS-induced” amendments occurred, Calcutta High Court had adjudicated *Dimminaco*\(^{33}\). Interestingly, pharma-product patents were, at that time, still not allowed. The bone of contention, therein, was a “process for preparation of infectious Bursitis Vaccine” whose “end product contained a living virus”\(^{34}\). IPO rejected it. The petitioners argued that “patent claimed is only for process and not the vaccine” and the refusal was based on “administrative policies” and was, therefore, wrong\(^{35}\). The Court considered aforementioned vaccine as “useful for protecting poultry against the contagious Bursitis infection” and, held that the “invention” satisfied the “Vendibility Test” which invariably “is satisfied if the invention results in the production of some vendible item” or saleable/ trade-able item, and if that is so “the process of manufacture involved in the invention” can be patented\(^{36}\). Court also held that,

“The Controller erred himself in law by holding that merely because the end product contains a live virus, the process involved in bringing out the end product is not an invention. The dictionary meaning of the word manufacture does not exclude the process of

\(^{32}\) The Patents Act, 1970 (Act 39 of 1970), s. 3(j), it says that, “The following are not inventions within the meaning of this Act” ... “(j)plants and animals in whole, or any part thereof, other than microorganisms but including seeds, varieties and species and essentially biological processes for production of plants and animals”.


\(^{34}\) Ibid.

\(^{35}\) Ibid.

\(^{36}\) Ibid.
preparing a vendible commodity which contains a living substance
and in a case like this where there is no statutory meaning of
manufacture, the dictionary must be accepted.”\textsuperscript{37}

It finally directed consideration of “the patent application” for grant “in the light of
observations made in this judgment”\textsuperscript{38}. This was indeed revolutionary. Today,
obviously, as we stated above, microbes are eligible.

**Vaccines, Antibiotics & the TRIPS Effect:** TRIPS mandated that,

“Members may also exclude from patentability” ... “(b) plants and
animals other than micro-organisms, and essentially biological
processes for the production of plants or animals other than non-
biological and microbiological processes.”\textsuperscript{39}

Hence, as Rimmer says, WTO members are “obliged to provide for patent protection
of microorganisms”\textsuperscript{40}. Such microbes must, obviously, be non-natural. This being so,
even EPC, therefore, grants patents thereon\textsuperscript{41}. Logically, all “antibiotics, vaccines,
insulin and diagnostic tools”\textsuperscript{42} relying on them, must also be patent-eligible. We do
reiterate that, in afore-stated cases, other monopoly-grant yardsticks must be fulfilled.

We now engage with plants.

**4.2. PLANT PATENTS**

Plants are defined as “any of a kingdom (plantae) of living beings typically lacking
the ability to move from place to place under their own power, having no obvious

\textsuperscript{37} Ibid.
\textsuperscript{38} Ibid.
\textsuperscript{39} TRIPS, 1994, Art. 27.3(b)
\textsuperscript{40} Supra 17 at 45
\textsuperscript{41} See, EPC, 2000, Arts. 52 and 53, nowhere, within EPC law are microorganisms excluded.
\textsuperscript{42} See, supra 8
nervous or sensory organs, and possessing cellulose cell walls and capacity for indefinite growth”\(^{43}\). In themselves these are, researcher humbly submits, more relevant from agri-biotech perspective. Plants do become relevant for pharma-bio when, as mentioned in our chapter 2, “active ingredients” of synthetic drugs are derived therefrom, or when drugs “derived from a natural product” are made. In those scenarios, the conundrum is not monopolisation of plant itself, which interestingly, and generally in such cases, might not even be sought. Rather, in such context, bio-stealing dilemma arises, which we engage with in our chapter 6. Hence, here we, only briefly engage with plant monopolies. Interestingly, within agri-bio also, prominence is given to something called “plant varieties”\(^{44}\). In varieties’ context, however, patenting rubric was *hitherto* considered inadequate. One commentator noted that,

> “Historically, the patent system was ill-adapted to plant varieties. Plant breeders first sought protection under the industrial patent system. However, a number of technical difficulties were encountered in seeking to apply the rules of a system designed to protect technical inventions to plant varieties, which were thought not to reproduce themselves precisely and whose appearance could vary depending upon the environment in which they are grown.”\(^{45}\)

\(^{43}\) *Supra* 1  
\(^{44}\) UPOV Convention, 1991, Art. 1 says that “plant varieties” mean that “a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for grant of a breeder’s right are fully met, can be, defined by the expression of the characteristics resulting from a given genotype or combination of genotypes; distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged”.

\(^{45}\) *Supra* 17 at 50
It has also been said that it wouldn’t “be in the public interest to permit such an extensive monopoly over plant varieties, given their communal importance”\(^\text{46}\). This led to a special system called, “International Union for the Protection of New Varieties of Plants” or “UPOV” which “was established in 1961 by the International Convention for the Protection of New Varieties of Plants (the UPOV Convention)”\(^\text{47}\).

It’s a \textit{sui generis} system mandating “each contracting party” to “protect breeder rights”\(^\text{48}\). It, therefore, is relevant for agriculture. Given our perspective, therefore, it is beyond our ambit. Interestingly TRIPS also provides that,

> “Members may also exclude from patentability” ... “(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective \textit{sui generis} system or by any combination thereof.”\(^\text{49}\)

Clearly, within “plant patents”, the afore-stated “plant varieties” are kept on a separate footing and for their protection, at least a “\textit{sui generis} system” must be there. One such system, we saw above, is UPOV. India, given the above flexibility, does not consider, as “inventions”, \textit{inter-alia}, the following,

> “Plants and animals in whole, or any part thereof other than micro-organisms but including seeds, varieties and species and essentially

\(^{46}\) Margaret Llewellyn, “The Legal Protection of Biotechnology Inventions: An Alternative Approach” 19(3) \textit{EIPR} 115-127 (1997), 117

\(^{47}\) Information available at www.upov.int/overview/en/upov.htm (last visited on December 09, 2016)

\(^{48}\) \textit{Supra} 44 Art. 2

\(^{49}\) \textit{Supra} 39
biological processes for production or propagation of plants and animals."\(^{50}\)

However, it did enact, the law, titled, “The Protection of Plant Varieties and Farmers’ Rights Act, 2001” (or “PVFRA”). This law, however, is relevant from agri-bio perspective and discussions thereon are, consequently, beyond our ambit. We now look at U.S. scenario.

**U.S. & Plant Monopolies:** Here, a cross-linked system exists. There is, firstly, law titled, “Plant Variety Protection Act, 1970” (or “PVPA”) which “provides legal intellectual property protection to breeders of new varieties of plants which are sexually reproduced (by seed) or tuber-propagated”\(^{51}\). This honours its UPOV commitments. Also, another law titled, “Plant Patent Act, 1930” (or “PPA”) exists. It, *inter-alia*, says that,

> “Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber-propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title”\(^{52}\).

The former grants Breeders’ rights and embraces “sexually reproduced” plants whereas the latter covers “asexually” manufactured plants. Interestingly, dilemma

\(^{50}\) *Supra* 32  
\(^{51}\) Information available at https://www.ams.usda.gov/rules-regulations/pvpa (last visited on December 08, 2016).  
\(^{52}\) 35 U.S.C. § 161
here was: Could, inspite of these afore-mentioned systems, a normal patent still be given? U.S.S.C. in *J.E.M. AG Supply* 53, expressed this dilemma as,

> “Whether” ... “patents may be issued for plants under 35 U.S.C. § 101 or whether the Plant Variety Protection Act” ... “and the Plant Patent Act of 1930” ... “are the exclusive means of obtaining a federal statutory right to exclude others from reproducing, selling, or using plants or plant varieties.” 54

Citing *In re Hibberd* 55 it said that,

> “Several years after Chakrabarty, the PTO Board of Patent Appeals and Interferences held that plants were within the understood meaning of manufacture or composition of matter and therefore were within the subject matter of § 101” ... “It has been the unbroken practice of the PTO since that time to confer utility patents for plants.” 56

Then it observed that,

> “In the face of these developments, Congress has not only failed to pass legislation indicating that it disagrees with the PTO’s interpretation of § 101; it has even recognized the availability of utility patents for plants.” 57

54 *Id.* at 127
56 *Supra* 53 at 130
57 *Id.* at 145
It then opined that “nowhere does the PVPA purport to provide the exclusive statutory means of protecting sexually reproduced plants”58 and also that “nothing” at all “indicates that the PPA’s protection for asexually reproduced plants was intended to be exclusive”59. Based on this, it held that “newly developed plant breeds fall within the terms of § 101, and that neither the PPA nor the PVPA limits the scope of § 101’s coverage”60. U.S., thus, is an anomaly, where, as elaborated above, three separate protection system exists. We now engage with EPC.

**The European Perspective:** EPC says that,

> “European patents shall not be granted in respect of:” ... “(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;”61

There are two strands to this. Firstly, “plant varieties” are obviously excluded. The ambiguity here is does this embrace “plants” *per se*? Secondly, “essentially biological processes for production of plants” are also obviously barred. Herein the ambiguity is does this embrace products from “essentially biological processes”?

The first dilemma was answered negatively, i.e. “plants” *per se* are not barred. EPO’s EBoA framed the query that “Does a claim which relates to plants but wherein specific plant varieties are not individually claimed *ipso facto* avoid the prohibition on patenting in Article 53(b) even though it embraces plant varieties?”62 It made distinction between “plant varieties” and “plants” and said that “varieties have been

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58 Id. at 138
59 Id. at 132
61 *Supra* 41 Art. 53(b)
62 G-0001/98 (EBoA, 1999), 1
generally considered to be the result of breeding process”

Contrary to this, for a “plant”, it observed that,

“In contrast, a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed” ... “It is not a concrete living being or grouping of concrete living beings but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part.”

It further elaborated that, “In the absence of the identification of a specific plant variety in the product claim, the subject matter of the claimed invention is not directed to plant variety or varieties within the meaning of Article 53 (b) EPC”. It also said that,

“Article 53(b) EPC defines the borderline between patent protection and plant variety protection. The extent of the exclusion for patents is obverse of the availability of plant variety rights. The latter are granted only for specific plant varieties and not for technical teachings which can be implemented in an indefinite number of plant varieties”.

Hence, a claim over plants but not over “specific plant varieties” thus “is not excluded from patentability”. It also clarified that “whether a plant variety is the result of traditional breeding techniques, or whether genetic engineering was used to obtain a

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63 Id. at 16
64 Id. at 17
65 Id. at 28
66 Id. at 29
67 Id. at 34
distinct plant grouping, does not matter for” plant breeders’ rights protection system,
and “a new plant variety bred as a result of genetically modifying a particular plant
variety is still excluded from patent protection, even if the genetic modification is the
result of a biotechnological process”.

Regarding second dilemma, much confusion exists. Initially, EBoA, in another
dispute, had opined that,

“The exclusion of essentially biological processes for the
production of plants in Article 53(b) EPC does not have a negative
effect on the allowability of a product claim directed to plants or
plant material such as a fruit.”

This is so even if “the only method available at the filing date for generating the
claimed subject-matter is an essentially biological process”. Products so made,
therefore, are still protection worthy. Recently, however, EPO issued a notice, inter-
alia, stating that,

“The European Commission adopted a notice” ... “With regard to
the patentability of plants and animals obtained by means of
essentially biological processes, the Commission takes the view
that in accordance with the EU legislator’s intention such plants
and animals are not patentable” ... “The President of EPO has
decided that, in view of the potential impact of the Commission
Notice, all proceedings before EPO examining and opposition
divisions in which the decision depends entirely on the

68 Id. at 32-33
69 G-0002/12 (EBoA, 2015), 68, Reiterated in G-0002/13(EBoA, 2015)
70 Ibid.
patentability of a plant or animal obtained by an essentially biological process will be stayed *ex officio*.”

Hence, the second issue, remains, unresolved. This demonstrates, researcher humbly submits, inherent arduousness of absolutely resolving dilemmas in bio-patents’ contexts. This is also shown by animal monopolies, as discussed now.

### 4.3. (TRANSGENIC) ANIMAL MONOPOLIES

Animals are defined as “any of a kingdom (Animalia) of living beings typically different from plants in capacity for active moment; in rapid response to stimulation; and in lack of cellulose cell walls” and as “one of the lower animals as distinguished from humans”

Transgenic animals, discussed herein, are relevant “in both genetics and stem cells” and also for medical research and xenotransplantation. We discuss their monopolisation conundrums, beginning with U.S. perspective.

#### 4.3.1. ANIMAL MONOPOLIES & USA

**The Polyploid Oysters:** Monopolies over so-called “higher life forms” materialised, in U.S. with *Ex parte Allen*. Here, on September 6, 1984, an application, *inter-alia*, claiming “a method of inducing polyploidy in oysters through the use of hydrostatic pressure” was filed. It covered “method of producing sterile

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72 Supra 1

73 Supra 17 at 82

74 This term has been extensively used, in context of animal and also plant monopolies. See, illustratively, *Commissioner of Patents v. President and Fellows of Harvard College* [2002] 4 R.C.S. 45

75 *Ex Parte Allen*, 2 USPQ 2d (1987)

pacific oysters, which are edible year round by inducing polyploidy in oysters”\textsuperscript{77} as well as “the oysters produced by that method”\textsuperscript{78}. Such “sterile pacific oysters” were, clearly, non-natural animals. USPTO, however, considered them as “controlled by laws of nature and not a manufacture by man that is patentable”\textsuperscript{79}. The appeal Board, however, said that,

“If the claimed subject matter occurs naturally, it is not patentable subject matter under § 101. The fact, as urged by the examiner, that the oysters as produced by the claimed method are controlled by the laws of nature does not address the issue of whether the subject matter is a non-naturally occurring manufacture or composition of matter. The examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man, nor has the examiner urged that polyploid oysters occur naturally”\textsuperscript{80}.

Finally it held that, “the claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter”\textsuperscript{81}. However, due to obviousness of “inducing polyploidy” as affirmed by “experts in the art”, the monopoly was not granted\textsuperscript{82}. In appeal, CAFC affirmed this.\textsuperscript{83}

\textsuperscript{77} For facts, see, \textit{In re Allen}, 846 F.2d 77 (CAFC, 1988)
\textsuperscript{78} \textit{Ibid}.
\textsuperscript{79} Facts as enumerated in \textit{supra} 75 at 1425
\textsuperscript{80} \textit{Ibid}.
\textsuperscript{81} \textit{Ibid}.
\textsuperscript{82} \textit{Ibid}.
\textsuperscript{83} \textit{Supra} 77
4.3.1.1. THE USPTO NOTICE: DAWN OF ANIMAL PATENTS

Consequently, USPTO issued a notice, titled, “Animals Patentability, 1077 O.G. 24” dated “April 7, 1987” wherein it said that,

“The Patent and Trademark Office now considers non-naturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 USC § 101” ... “Accordingly the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human non-naturally occurring manufacture or composition of matter: a product of human ingenuity, such claims will not be rejected under 35 USC § 101 as being directed to non-statutory subject matter.”

It did say that “products found in nature will not be considered patentable subject matter”. The notice was challenged on some technical and administrative grounds (grounds which are un-related to our research). Courts rejected the challenges. It remains, therefore, the current USPTO policy.

4.3.1.2. THE “HARVARD ONCOMOUSE” & U.S.A.

The battle over monopolising so-called “Harvard Oncomouse” occurred in three jurisdictions- Canada, EPO and U.S. It originated in U.S. where Patent No.

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85 Ibid.
“4736866” got granted sans conundrums or objections. It was titled, “Transgenic Non-Human Mammals” with “Philip Leder and Timothy Stewart” as the “inventors” and the “President and Fellows of Harvard College, Cambridge, Massachusetts” listed as the “assignees”\textsuperscript{88}. It claimed, \textit{inter-alia},

“A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of the said mammal, at an embryonic stage”\textsuperscript{89}.

It covered, therefore, all “transgenic non-human mammal”. Its claims 11 and 12 covered respectively, “the mammal of claim 1, said mammal being a rodent” and also “the mammal of Claim 11, said rodent being a mouse”\textsuperscript{90}. The patent also stated that “the presence of the oncogene sequence in the germ cells of the transgenic founder animal in turn means that all of the founder animal’s descendants will carry the activated oncogene sequence in all of their germ cells and somatic cells.”\textsuperscript{91} Such mice “could be used to test a material suspected of being a carcinogen, by exposing the animal to the material”\textsuperscript{92} and also for cancer treatment\textsuperscript{93}. Shockingly, as aforementioned, the patent covered progeny also. In essence, a living being was reduced to a “commodity” whose generations were Harvard’s property. We now look at fate of “Harvard oncomouse” at EPO.

\textsuperscript{88} See, U.S. Patent No. “4736866”
\textsuperscript{89} Id. Claim 1
\textsuperscript{90} Id. Claims 11 and 12
\textsuperscript{91} Id. “Summary of the Invention”
\textsuperscript{92} Ibid.
\textsuperscript{93} Ibid.
4.3.2. EPC & ANIMAL MONOPOLIES

As we showed earlier in part 4.2., in animals’ context as well, EPC disallows “animal varieties” from being monopolised\(^{94}\). Curiously, it allows “animal patents” by making, as we show, distinction between “animal varieties” and “animals”. It was first carved out in, unsurprisingly, the *Oncomouse* matter. Interestingly, even though monopoly therein was granted\(^ {95} \), yet it had much turbulent journey. Initially, refused in 1989\(^ {96} \), application lingered for about 15 years! In 2004, final adjudication came, and, the monopoly expired in 2005. Also, in between, even the EUBD came about. Interestingly, even EPC, in between, got amended\(^ {97} \). We deal here with only final re-evaluations. During that, several oppositions were also initiated\(^ {98} \). Consequentially, scope of monopoly was narrowed from “all non-human mammals” to “transgenic rodents”. And finally, it got narrowed from “transgenic rodents” to “transgenic mice”.\(^ {99} \) We briefly summarize the final rationale offered,

“**Animal**” v. “**Animal Varieties**”: EPO stated that “there is no excluded or excepted category of animals in general”\(^ {100} \). It reasoned that patents to whole “animal varieties” are denied but are allowed to “animals in general”\(^ {101} \).

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\(^{94}\) *Supra* 41 Art. 53(b)

\(^{95}\) European Patent No. “EP0169672”

\(^{96}\) It was refused by EPO’s Examining Division

\(^{97}\) EPC, 1973 became EPC, 2000. Interestingly, EPC Regulations, 2006, r. 28(d) says that “Under A. 53(a), European Patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following” … “(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without substantial medical benefit to man or animal, and also animals resulting from such processes”.

This corresponds to erstwhile r. 23d (d).

\(^{98}\) T-315/03 (EPO TBA, 2004), 4, it says that “between 18 December 1992 and 13 February 1993 seventeen oppositions were filed alleging”, *inter-alia*, “lack of industrial application, lack of novelty and the inventive step, the absence of an invention, a non-patentable method for treatment of the animal body”. But all were dismissed.

\(^{99}\) See decision in *ibid*.

\(^{100}\) *Id.* at 70

\(^{101}\) *Ibid.*
The “Ordre Public or Morality” parameter: EPO endorsed that “ordre public” implies protecting “physical integrity of individuals” and environmental protection\textsuperscript{102}. For the latter, EPO concluded that “no conclusive evidence” was given to indicate “threat to environment” or even “threat to evolution” itself.\textsuperscript{103} In morality’s context, it said that,

“This case is concerned neither with the morality of genetically manipulating a mouse nor with the morality of the oncomouse thereby produced nor with the morality of patenting either the oncomouse or the genetic manipulation method but only with the morality of publication or exploitation of the invention”\textsuperscript{104}.

It elaborated that, “the concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture” and in this case that culture is “the culture inherent in European society and civilisation”\textsuperscript{105}. For this “European morality”, question was how to find it? For this, EPO was given some opinion polls’ results. But it stated that, “No information was put forward about the methodology of such polls, for example, whether they were conducted by trained professional pollsters or by casual staff recruited for the particular poll in question”\textsuperscript{106}. It thus rejected their authenticity.

Animal “Suffering” v. Benefits: EPO agreed that, within European culture (and hence, “morality”) animals “are respected as sentient beings” not to be “abused” or

\textsuperscript{102} Id. at 95
\textsuperscript{103} Id. at 116-119
\textsuperscript{104} Id. at 68-69
\textsuperscript{105} Id. at 95
\textsuperscript{106} Id. at 124
“misused”\textsuperscript{107}. But their inevitable “suffering” was “balanced” against the obvious benefit of “furtherance of cancer research”. This benefit to “cancer research” was held to be more substantial and “suffering” was necessarily accepted\textsuperscript{108}. The monopoly was, thus, given. Interestingly, “animal suffering” was pitied against “substantial medical benefits” and the former lost, unsurprisingly perhaps because human judges decided based on human convenience. Nevertheless, it paved way for animal monopolies within Europe. Interestingly quite a different fate awaited “Harvard Oncomouse” in Canada as we now show.

\textbf{4.3.3. CANADA & ANIMAL MONOPOLIES}

Canadian perspective is studied by us primarily for “Harvard Oncomouse” decision as determined by their Supreme Court\textsuperscript{109}. Its trajectory was anything but smooth\textsuperscript{110}. Its apex court formulated that,

\begin{quote}
“The sole question is whether parliament intended the definition of invention and more particularly the words manufacture or composition of matter, within the context of patent act, to encompass higher life forms such as the oncomouse.”\textsuperscript{111}
\end{quote}

Considering their law\textsuperscript{112}, the majority answered that, “The parliament did not intend higher life forms to be patentable”.\textsuperscript{113} Nevertheless, throughout the decision, the

\begin{itemize}
\item \textsuperscript{107} \textit{Id. at 127}
\item \textsuperscript{108} \textit{Id. at 112-113}
\item \textsuperscript{109} \textit{Supra 74}, it was given by 5:4 majority.
\item \textsuperscript{110} The judgment notes that “the Commissioner of Patents upheld the Patent Examiner’s refusal to grant the patent. This decision was in turn upheld by the Federal Court, Trial Division, but was overturned by a majority of the Federal Court of Appeal” see, \textit{Id. at 104}
\item \textsuperscript{111} \textit{Id. at 105}
\item \textsuperscript{112} Canada’s Patent Act, 1985, s. 2 says that “Invention means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter”.
\item \textsuperscript{113} \textit{Supra 74 at 105}
\end{itemize}
amazing struggle with competing conundrums and perspectives and interests is markedly evident. We summarize, herein, the debates’ main strands,

**The “Pro-Patent” Perspective:** This stance was taken by a lower court and is best summarized as,

“The length of a tail, colour of eyes or texture of fur is irrelevant to the usefulness of the invention. All that is relevant to the usefulness of the product in this case is that a mouse is produced with all of its cells affected by the oncogene” ... “the fact that other characteristics of the oncomouse are not reproducible by will by the inventor or a person skilled in the science is irrelevant because they are not necessary for the usefulness of the oncomouse”\(^ {114}\).

But ultimately, majority disregarded afore-quoted perspective.

**The “Anti-Patent” Stand:** Majority considered eligibility of “higher life forms” as “a matter for parliament to determine”\(^ {115}\). It also said that,

“Parliament did not intend higher life forms to be patentable. Had the parliament intended every conceivable subject matter to be patentable, it would not have chosen to adopt an exhaustive definition that limits invention to any art, process, machine, manufacture or composition of matter. In addition, the phrases

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\(^{114}\) See, *id.* This view of Federal Court of Appeal was extensively dealt in majority judgment.

\(^{115}\) *Id.* at 121
manufacture and composition of matter do not correspond to common understandings of animal and plant life.”

Clearly, here, majority was giving deference to their “parliament”. In dramatic contrast to U.S. position, it held that,

“Although some in the society may hold the view that higher life forms are mere compositions of matter, the phrase does not fit well with common understandings of human and animal life. Higher life forms are generally regarded as possessing qualities and characteristics that transcend the particular genetic material of which they are composed” ... “The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere composition(s) of matter. It is a phrase that seems inadequate as a description of a higher life form”.

Further, it stated that,

“Patenting higher life forms would involve a radical departure from the traditional patent regime. Moreover, patentability of such life forms is highly contentious matter that raises a number of extremely complex issues. If higher life forms are to be patentable, it must be under the clear and unequivocal direction of the Parliament.”

116 Id. at 105
117 Id. at 127- 128
118 Id. at 129
It further noted that, “Unlike other inventions, biologically based inventions are living and self-replicating” and, therefore, “Patent Act in its current state is ill-equipped to deal appropriately with higher life forms as patentable subject matter”\textsuperscript{119}. Majority also admitted, rather candidly, Supreme Court’s “institutional incompetence” in such complex issues\textsuperscript{120}. This, clearly, stands in contrast to U.S. approach in \textit{Chakrabarty}. This deference might be, it is submitted, wise and sensible because such bewilderingly socio-technical conflicts need elaborate considerations and judges aren’t trained to consider those.

**Canada’s Current Positioning:** Interestingly, around that time, one Canadian Committee\textsuperscript{121} had recommended, \textit{inter-alia}, that “Higher Life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be made patentable”\textsuperscript{122}. Canadian Patent Law, interestingly, was never amended to reflect this. Therefore, its current Patent Practice Manual says that, “Higher Life forms are excluded from patentability”\textsuperscript{123}. It elaborates that, “animals at any stage of development are not statutory subject matter eligible for patent” and, on this logic, it also excludes “fertilized eggs” as well as “totipotent stem cells” but not animal/plant ESCs\textsuperscript{124}.

### 4.3.4. TRIPS, ANIMAL MONOPOLIES & INDIA

As seen in foregoing parts, TRIPS says that, “Members may also exclude from patentability” \textit{inter-alia} “(b) plants and animals”.\textsuperscript{125} Hence, “animal patents” are made discretionary. India, using this flexibility, excludes, \textit{inter-alia}, “animals in whole or

\textsuperscript{119} Id. at 130-131
\textsuperscript{120} Id. at 139
\textsuperscript{121} It is named, “Canadian Biotechnology Advisory Committee” (henceforth, CBAC)
\textsuperscript{122} CBAC, “Patenting of Higher Life Forms and Related Issues” 11 (June, 2002)
\textsuperscript{123} Canadian Patent Office, “Manual of Patent Office Practice”, Part 12.05.03
\textsuperscript{124} Id. parts 12.05.03 and 17.02.01
\textsuperscript{125} Supra 39
any part thereof”.  

It also excludes “seeds, varieties and species and essentially biological processes for production of plants and animals”\textsuperscript{127}. IPO also maintains that claims covering “development stages of plants and animals shall be objected under section 3 (j)”\textsuperscript{128}. We, therefore, now see monopolisation of animal clones.

### 4.4. ANIMAL CLONING MONOPOLIES: JURISDICTIONAL PERSPECTIVE

We must, in animals’ context, briefly dwell on cloning thereof. Detailed engagement with cloning, including multitudinous predicaments or concerns raised there-under, follows when researcher, in a subsequent part, analyzes human clones. Interestingly, as regards animals, it is stated that,

“It was not until 1996, however, that researchers succeeded in cloning the first mammal” ... “Two years later, researchers in Japan cloned eight calves from a single cow, but only four survived. Besides cattle and sheep, other mammals that have been cloned from somatic cells include cat, deer, dog, horse, mule, ox, rabbit and rat.”\textsuperscript{129}

The technique, however, remains imperfect and many are “born with abnormalities”\textsuperscript{130}. In Indian context also, it’s reported that,

“World’s first cloned buffalo Garima delivered its second calf at the National Diary Research Institute (NDRI), Karnal, last week” ... “NDRI has produced the world’s first cloned buffalo female

\textsuperscript{126} Supra 32  
\textsuperscript{127} Ibid.  
\textsuperscript{128} Office of CGPDTM, “Guidelines for Examination of Biotechnology Applications for Patent” 15-16 (March, 2013)  
\textsuperscript{129} Information available at https://www.genome.gov/25020028/cloning-fact-sheet/ (last visited on December, 10, 2016)  
\textsuperscript{130} A. Lakshminath, “Stem Cell Patenting: Law and Policy” 49(2) JILI 179-193 (2007), 189
calf in 2010. Garima was born on August 22, 2010 using embryonic stem cells through hand guided cloning technique.”

But given our focus, we now solely analyze, from patenting perspective, the varied jurisdictional positions.

**U.S. Perspective:** Here, CAFC, in *Roslin*[^132], elegantly encapsulated, cloning’s history. It stated that,

> “On July 5, 1996, Keith Henry Stockman Campbell and Ian Walmut successfully produced the first mammal ever cloned from an adult somatic cell: Dolly the Sheep” … “The cloning method Campbell and Wilmut used to create Dolly constituted a breakthrough in scientific discovery”[^133].

Patent No. “7514258” was given over afore-quoted “method”. It covered, *inter-alia,* “A method for producing a mammalian cultured inner cell mass cell by nuclear transfer”[^134]. Procedures are, hence, clearly eligible. We now deal with Dolly itself, i.e. the product. For that, “examiner issued a non-final rejection” that the appeal “Board affirmed”[^135]. CAFC also “affirmed” rejection[^136]. Relying on “product of nature” concept, it stated that,

> “Dolly herself is an exact genetic replica of another sheep and does not possess markedly different characteristics from any farm

[^131]: Anita Singhl, “World’s first cloned buffalo Garima delivers second calf at NDRI” Times of India, Jan 3, 2015
[^132]: *In re Roslin Institute* 750 F.3d 1333 (CAFC, 2014)
[^133]: *Id.* at 1333-1334
[^134]: U.S. Patent No. “7514258” Claim 1
[^135]: *Supra* 132 at 1335
[^136]: *Id.* at 1338
animals found in nature” ... “Dolly’s genetic identity to her donor parent renders her unpatentable”\(^\text{137}\).

Hence, clearly, “animal clones” are ineligible.

**European Scenario:** Regarding Europe, it’s reported that,

“European Parliament” ... “voted to ban the cloning of all farm animals as well as the sale of cloned livestock, their offspring, and products derived from them”\(^\text{138}\).

It being so, patenting, we submit, logically, gets rendered impossible. But if they are not afore-mentioned “farm animals”, could they be monopolised? We humbly argue that unless “Product of Nature” reasoning is also taken by EPO, they could be. Interestingly, methods or procedures, we humbly state, could be eligible.

**Indian Perspective:** About India, we already discussed that “animals in whole”\(^\text{139}\) are ineligible. Therefore, cloning products (meaning “animals”) consequently get barred. Regarding methods thereof, surprisingly, IPO is quite clear. Within “public order or morality”\(^\text{140}\) clause, its Guidelines\(^\text{141}\) include “a process for cloning human beings or animals” as “non limiting example” of what is excluded\(^\text{142}\).

Admittedly, much obfuscation, unresolved dilemmas, and polarised perspectives exist, as we highlighted above, in “higher life forms” patents’ context. Having dealt till here, with them and, also, with microbes, we next focus on Homo sapiens.

\(^{137}\) *Id.* at 1337


\(^{139}\) *Supra* 32

\(^{140}\) *Id.* s. 3(b), it says that “The following are not inventions within the meaning of this Act” ... “(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment”.

\(^{141}\) *Supra* 128

\(^{142}\) *Id.* at 11
4.5. TRANSGENIC HUMAN BEINGS & HUMAN CLONES

Human beings, whether genetically altered or cloned, are, we humbly submit, within patent law, perhaps, the only universally sacrosanct, non-eligible matter. It must, in this context, be understood that references to so-called “human patents” necessarily imply only cloned homo-sapiens or transgenic-humans. To even think that an unaltered or natural homo-sapien could be monopolised, is absolutely illogical. Hence, where laws bar aforesaid “human patents”, they actually bar monopolies over GM-humans or clones. Moreover, technically, humans are animals. They could, therefore, arguably, be covered under exclusion for “plants and animals”. However, in patent jurisprudence, humans are not so categorized. Indeed, human beings are a category in themselves. In this background, researcher looks at monopolies over GM-humans and human clones.

4.5.1. TRANSGENIC HUMAN BEINGS

In all jurisdictions, genetically altering humans is, from a legal perspective, almost impossible. It is, consequentially, improbable to monopolise a complete human body, as we now herein show. Moreover, here, the bar is on product, i.e., the GM-human, and not necessarily on procedures, which might very well be same as, or identical to, those used for creating other GM-species. We now analyse the major jurisdictions.

4.5.1.1. CHIMERAS & TRANSGENIC HUMANS: U.S. PERSPECTIVE

In U.S., an experimental application, titled, “Chimeric embryos and animals containing human cells” and controversially claiming, inter-alia, “a chimeric

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143 Supra 39
144 U.S. Patent Application No. “0030079240”. The invention did not exist. The inventors/applicants merely wanted to, by their own admission, raise or highlight issue of so-called “human patentability”. See, supra 17 at 98-103
embryo comprising cells from a first and one or more second animal species, wherein said first animal species is human, wherein said second animal species is non-human, and wherein said second animal species is non-primate,"¹⁴⁵ was filed. USPTO objected thereto, and ultimately the applicants abandoned it. Of course, being hypothetical and more of a sensationalist misadventure, there was never any real danger, but the application did raise alarming and interesting questions¹⁴⁶. One conundrum was, could human beings or human-animal “chimeras” be monopolised? It can be said that, inspite of an “anything under the Sun that is made by man” credo, even for U.S., as elsewhere, humans are sacrosanct. The answer to aforesaid conundrum was, therefore, “No”. At present, the law titled, “The Leahy-Smith America Invents Act, 2011” (henceforth, “AIA”) categorically states that,

“Nowithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.”¹⁴⁷

Interestingly, AIA was enacted “to provide for patent reform”¹⁴⁸, and the aforesaid bar applies to even the pending applications¹⁴⁹. We now look at Canadian regime.

4.5.1.2. TRANSGENIC HUMANS & CANADA

Here, CBAC considered, succinctly and, at length, this dilemma of GM-humans¹⁵⁰. It opined that, “Human bodies at all stages of development should be excluded”¹⁵¹. But, it noted that, “human DNA sequences, gametes, stem cells, organs” etc. might be

¹⁴⁵ Id. Claim 1
¹⁴⁶ For detailed discussion, see, supra 17 at 98-103
¹⁴⁷ AIA, 2011, s. 33(a)
¹⁴⁸ The long title of AIA says that “To amend title 35, United States Code, to provide for patent reforms”.
¹⁴⁹ See, id. s. 33(b) titled “Effective date”
¹⁵⁰ Supra 122 at 8-10
¹⁵¹ Id. at 8
allowed\textsuperscript{152} since, CBAC opined that, blanket ban, without any space for future manoeuvring or flexibility, could be harmful. This enabled, as per CBAC, patenting of, and, therefore, research in, “artificially created human organs” and “stem cells”\textsuperscript{153}. The reasons (these reasons are basically universal) for exclusion of human beings, were stated as,

1. Exclusion is based on “respect for human dignity” which is “source of all human rights”\textsuperscript{154}.
2. It prevents “commodification” or monopolies over “human” body\textsuperscript{155}.
3. Monopolistic dealings in human body/bodies tantamount to slavery or “violate Canadian Charter of Rights and Freedoms and the Canadian Human Rights Act”\textsuperscript{156}.

We now see the European situation.

\textbf{4.5.1.3. TRANSGENIC HUMANS & EPC}

Here, EPC’s regulations categorically say that,

“The human body, at the various stages of its formation and development, and the simple discovery of one of its elements” ... “cannot constitute patentable inventions.”\textsuperscript{157}

This, however, does not extend to “an element isolated from the human body or otherwise produced by means of a technical process”\textsuperscript{158}. The “element”, as is later

\begin{flushright}
\textsuperscript{152} \textit{Id. at 9} \\
\textsuperscript{153} \textit{Ibid.} \\
\textsuperscript{154} \textit{Id. at 8} \\
\textsuperscript{155} \textit{Ibid.} \\
\textsuperscript{156} \textit{Ibid.} \\
\textsuperscript{157} \textit{Supra 97 r. 29(1)} \\
\textsuperscript{158} \textit{Id. r. 29(2)}
\end{flushright}
clarified, includes, “sequence or partial sequence of a gene”\(^{159}\). These latter are covered in our chapter 5. It is clear that aforesaid embargo or prohibition on patenting “human body, at the various stages of its formation” means barring of both GM-humans and clones. This rule reflects the identically worded EUBD clause\(^ {160}\). Infact, in this context, the entire EPC reflects nothing but EUBD’s stance on “the human body” and its constituent “elements”\(^ {161}\). Moreover, EPC regulations also say that, “European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following” … “(b) processes for modifying the germ line identity of human beings”.\(^ {162}\)

This is also a reiteration of an identical EUBD clause\(^ {163}\). Hence, both transgenic humans and manufacturing methods thereof are barred. Let’s now see India’s situation.

**4.5.1.4. TRANSGENIC HUMANS & INDIA**

India, surprisingly, has no express bar on either creating GM-humans or monopolising them. However, ICMR in its Guidelines titled, “Ethical Guidelines for Biomedical Research on Human Participants, 2006” includes within “Prohibited Areas of Research”, the following, i.e., “Any research related to germ line genetic engineering or reproductive cloning”.\(^ {164}\) Therefore, “germ line genetic engineering” is barred. But these are mere guidelines. Given Indian ethos, however, even without an express bar,

\(^{159}\) *Ibid.*

\(^{160}\) EUBD, 1998, Art. 5(1) says that “The human body, at the various stages of its formation and development, and the simple discovery of one of its elements” … “cannot constitute patentable inventions”.

\(^{161}\) See, *Id.* Arts. 5(2) and 5(3)

\(^{162}\) *Supra* 97 r. 28(b)

\(^{163}\) *Supra* 160 Art. 6(2)(b)

\(^{164}\) ICMR, “Ethical Guidelines for Biomedical Research on Human Participants” 93 (2006)
it is highly unlikely, we humbly opine, that such researches will ever be legally sanctioned or funded. In patenting context, it will also be hit by “public order or morality” exclusion which says that,

“The following are not inventions within the meaning of this Act”

...“(b) an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment”\(^\text{165}\).

We can argue that GM-humans will cause “serious prejudice to human life or health”, since we do not know the exact and long-term consequences of so altering humans or the psychological suffering such a transgenic-human will have to endure. Moreover, doing so would be “contrary to public order or morality” given Indian society’s religious, ethical and spiritual roots. Also, IPO’s Guidelines include “a process for modifying the germ line of human beings” as “non-limiting example” of what can be excluded\(^\text{166}\). Hence, such procedures or techniques are also excluded. We, hereinafter, assess other limb of conundrum, i.e. Human Clones.

4.5.2. HUMAN CLONES: A DUPLICATING CONUNDRUM

In our chapter 2, we had discussed cloning. Also, we had described the technique involved therein, called “somatic cell nuclear transfer” or “SCNT”. Also, in context of humans, we saw its two types, “therapeutic cloning” and “reproductive cloning” wherein the latter is highly dilemmatic since it involves “making cloned human beings”\(^\text{167}\). Now, we first look briefly at dilemmas or concerns around “reproductive

\(^{165}\) Supra 32 s. 3(b)

\(^{166}\) Supra 128 at 11

\(^{167}\) Firdos Khan, Biotechnology Fundamentals 310 (CRC Press, Florida, 2012)
cloning” which for our endeavour, we henceforth refer to simply as cloning. Thereafter, we discuss the monopolisation dilemmas.

4.5.2.1. CLONING: THE CONUNDRUMS

Human clones are a thorny issue, and, unsurprisingly, evoke fear, bewilderment and loath. Proponents argue that “cloning could assist couples who are both infertile”\(^{168}\). But then why should they not adopt? Also, it is argued that clones are solution for “current problems of rejection in organ transplants” and should be constructed for that purpose\(^{169}\). But if clone is manufactured “solely for the purpose of providing spare parts (i.e. organ transplantation)” then this will “contradict human dignity”\(^{170}\). Also, are we not “commodifying life” here? It is further stated that “a dying child” could be so duplicated\(^{171}\). Does this mean that a person could, through such duplication, live infinitely? This will be, researcher humbly opines, gross interference with nature. Its implications are unimaginable. A very basic conundrum here is, has human species “started playing God”\(^{172}\)? But such sensationalism aside, complex and real dilemmas exist. Illustratively, cloning “challenges traditional notions of reproduction and parenthood” and one would find it difficult to answer, “Who” are the “parents of the clone”?\(^{173}\) Also, who really is the clone, is it a mere manufactured copy? Or does it have “moral rights”, and human dignity?\(^{174}\) Considering these conundrums, unsurprisingly, this “reproductive cloning” is largely banned, as we now see.

\(^{168}\) Ajai Kumar, “Human Cloning: A Socio-Legal and Ethical Appraisal” 52(1) JILI 92-109 (2010), 95
\(^{169}\) Ibid.
\(^{170}\) Id. at 97
\(^{171}\) Id. at 96
\(^{172}\) This phrase is oft-repeated in deliberations regarding “Genetic manipulation” and “cloning”. Illustratively, see, Pallava Bagla, “Should India ban human cloning?” (June 24, 2009) available at www.ndtv.com/offbeat/should-india-ban-human-cloning-396637 (last visited on January 14\(^{17}\), 2017)
\(^{173}\) Supra 168 at 99
\(^{174}\) Id. at 97-98
4.5.2.2 HUMAN CLONING & USA

In U.S., no specific prohibition exists. This being so, we focus on patenting of such human clones. As afore-discussed, under U.S. law “no patent may issue on a claim directed to or encompassing a human organism”. This should logically cover human clones also. Moreover, if a clone is “genetically identical” to a homo sapien, it arguably becomes akin to a “product of nature” and can be again rejected. As regards procedures or method thereof, a dilemma exists. There is no express bar. Such monopolies could, hence, exist. Illustratively, Patent No. “6781030” covers “a method of cloning a mammal”. This could arguably encompass humans also. But the claim in “6781030” includes only “a method of cloning a non-human mammal”. We humbly submit that arguably such “method of cloning a mammal” would be usually common across mammalian species and no real difference arises by excluding or not excluding humans since even if it mentioned “methods of cloning a non-human mammal”, someone could be tempted to apply it to manufacture human clones. But whether someone actually does or even attempts it is different issue. Admittedly in absence of clear bars on monopolizing methods, such anomalies can exist. Therefore, clear and specific prohibitions or interdicts must exist. We now look at European context.

4.5.2.3. HUMAN CLONING & EPC

175 Id. at 101, the author maintains that “there are currently no federal laws in United States which ban cloning completely”. This is true even now.
176 Supra 147
177 U.S. Patent No. “6781030” Claim 1, it is titled, “Methods for cloning mammals using telophase oocytes”.
178 A similar problem arose in context of US Patent No. “6211429” owned by University of Missouri
179 Supra 177 Claim 20
In 2009, in EU, a “legally binding” charter titled, “Charter of Fundamental Rights of the European Union” came into force. In dealing with “Right to integrity of the person”, it said that,

“In the fields of medicine and biology, the following must be respected in particular” ... “(d) the prohibition of the reproductive cloning of human beings”.

Moreover, EU Convention on Human Rights and Biomedicine’s protocol titled, “Additional Protocol on the Prohibition of Cloning Human Beings, 1998” also says that,

“Any intervention seeking to create a human being genetically identical to another human being, whether living or dead is prohibited.”

Such a “genetically identical human being” is nothing but a reproductive clone. Creating it, as aforesaid, is, therefore, barred. However, U.K. and Germany are yet to sign, and France is yet to ratify the aforesaid protocol, but several other European countries have adopted it. Since making “genetically identical” humans is barred, unsurprisingly, monopolistic protection thereof is also non-existent. Unsurprisingly, both EPC and EUBD spell out clear rules. The former says that,

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181 Charter of Fundamental Rights of the EU, 2000, Art. 3(2)(d)
“European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following (a) processes for cloning human beings”\textsuperscript{184}.

This reiterates the identical EUBD clause\textsuperscript{185}. As discussed above, EPC regulations also say that,

“The human body, at the various stages of its formation and development” ... “cannot constitute patentable inventions”\textsuperscript{186}.

As afore-discussed, this exclusion can be logically interpreted to embrace, \textit{inter-alia}, cloned humans. In this way, Europe possesses, in human clones’ context, the most unambiguous legal interdict. We now focus on Indian situation.

\textbf{4.5.2.4. HUMAN CLONING MONOPOLIES & INDIA}

As per the above-quoted ICMR Guidelines, “Any research related to germ line genetic engineering or reproductive cloning”\textsuperscript{187} is barred. It is clear that creating an identical homo sapien will remain a legal impossibility in India, even in absence of any express bars. ICMR also includes within “Prohibited Areas of Research”, the following, i.e. “Transfer of human blastocysts generated by SCNT or parthogenetic or androgenetic techniques into a human or non-human uterus”\textsuperscript{188}. It further says that,

“The possibility of human cloning cannot be rejected since sheep and mice have already been cloned. However, since its safety, success, utility and ethical acceptability is not yet established,

\begin{flushleft}
\textsuperscript{184} Supra 97 r. 28(a)  
\textsuperscript{185} Supra 160 Art. 6(2)(a)  
\textsuperscript{186} Supra 97 r. 29(1)  
\textsuperscript{187} Supra 164  
\textsuperscript{188} Ibid.
\end{flushleft}
research on cloning with intent to produce an identical human being, as of today is prohibited”.

Research being so “prohibited”, patent grant thereon is, obviously, unfathomable. The clone (i.e. the product) will undoubtedly fail the “public order or morality” threshold. As regards the methods, in context of “public order or morality” clause, IPO’s guidelines include “a process for cloning human beings” as “non-limiting examples” of valid exclusions. We now analyze xenotransplantation patenting.

4.6. XENOTRANSPLANTATION MONOPOLIES: JURISDICTIONAL PERSPECTIVES

In our chapter 2, we had discussed xenotransplantation and also engaged with the multitudinous conundrums and dilemmas associated therewith. Here, we assess its patent-eligibility. Two components exist to this assessment. Firstly, the animals used therein, who are invariably altered or modified, and, secondly, the xenotransplantation process, and resulting xeno-organs. As regards the former, i.e., GM-animals, their eligibility has been discussed above. We, therefore, look at the latter component. Moreover, there further exist two clear strands. First, is the technology acceptable and legal? Secondly, is monopolisation thereof allowed? If first answer is negative, obviously, and logically, monopolisation would be impossibility. We begin with U.S. perspective

**Xenotransplant Patenting & USA:** USA appears comparatively more approving of both xenotransplants and patents thereon. Infact, its USFDA had issued guidelines titled “Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of

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189 Id. at 101-102
190 Supra 32 s. 3(b)
191 Supra 128 at 11
Xenotransplantation Products in Humans: Guidance for Industry”, wherein, considering the risks involved, it said that “A plan for clinical follow-up of recipient” has to be submitted in context of “xenotransplantation” and this plan must “extend for the life of the recipient”192. Coming to patents, surprisingly, there exist quite a few. Illustratively, U.S. Patent No “6030833” titled “Transgenic swine and swine cells having human HLA genes” exists193. There exists another one, titled “Method for producing transgenic animals for xenotransplantation expressing both an enzyme masking or reducing gal epitope and a complement inhibitor”194. The latter’s first claim says that,

“(1) A method of preparing organs, tissues, or cells for xenotransplantation into human patients with reduced rejection comprising steps of (a) providing a transgenic pig which is source of transplant material which is anatomically and physiologically compatible with a human patient, said material selected from the group consisting of organs, tissues, or cells”195.

Moreover, there are also pending applications. Illustratively, one is titled, “Genetically Modified Pigs for Xenotransplantation of Vascularised Xenografts and Derivatives”196. It claims both “a transgenic animal”197 suitable for xenotransplants and also procedure “for xenotransplantation comprising administering, to a primate in need thereof, porcine organs, tissue or cells derived from an animal that lacks any expression of functional alpha 1, 3 galactosyltransferase (GTKO) and that

192 USFDA, “Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans: Guidance for Industry” 50 (April, 2003), These were updated on Dec. 2016
194 U.S. Patent No. “6166288”
195 Id. Claim 1
196 U.S. Published Application No. “US2014001725A1”
197 Id. Claim 1
specifically expresses at least one transgene in endothelial tissue."198 Such a “primate”, it claims can also be “human”199. The easy existence, in U.S., of aforementioned patents could be attributed, in researcher’s humble opinion, to lack of so-called “morality clause” in their patent law and their credo of “anything under the Sun that is made by man is patentable”. We now assess other jurisdictions, which, unsurprisingly, are more circumspect.

**Xenotransplant Monopolies & Europe:** Currently, Council of Europe has, in existence, “Recommendation: Rec 2003(10)”200 which lays broad guidelines that embrace “all xenotransplantation activities involving human beings as recipients”201. It states that,

“Xenotransplantation is defined as any procedure that involves the transplantation or infusion into a human recipient of live animal cells, tissues or organs, or human body fluids, cells, tissues or organs that have had *ex vivo* contact with live animal cells, tissues or organs”202.

It further states that,

“No xenotransplantation activity should be carried out in a member state unless authorisation is given by a body officially recognized

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198 *Id.* Claim 43
199 *Id.* Claim 45
201 *Id.* Art. 2
202 *Id.* Art. 3
as competent for this purpose, in accordance with the provisions contained in the following two paragraphs. So for each member country, such a separate “officially recognized body” must give authorisations. However, it appears that actual transplants are not generally encouraged. Illustratively, the second of the “two paragraphs” alluded to above is critical and says that, “Xenotransplantation should not be authorised other than in clinical research unless, on the basis of clinical data (i) there is adequate evidence, in accordance with internationally accepted scientific standards, that no risks, in particular of infection, to the general population exist, and (ii) the therapeutic benefits of the xenotransplantation has been established.

Clearly authorisation is to be given solely for “clinical research” unless exceptions stipulated above exist. However, these are, we humbly submit, mere non-binding recommendations. At a future time, when xenotransplants do get perfected or become feasible, patenting concerns will arise. We are more concerned with those. Illustratively, how this technology is assessed within EPC framework? We now assess the same.

Although EPC regulations bar “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes” but it can be argued that xenotransplantation indeed has such a “substantial medical benefit to

\[203\] Id. Art. 5
\[204\] Id. Art. 5(2)
\[205\] Supra 97
man” and hence processes thereof are eligible. GM-animals, researcher showed above, are already permitted on this rationale. So, there might be negligible hurdle in obtaining such monopolies. EPC also provides that “an element isolated from the human body or otherwise produced by means of a technical process” inter-alia “may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”206. Based on this, xeno-organs, researcher argues, could also be eligible. We next assess the Indian scenario.

**Xenotransplant Monopolies & India:** Given Indian ethos, Indian morality, the multitudinous technical imperfections, and xenotransplants’ inherent repulsiveness, we humbly opine that acceptability thereof shall remain low. Unsurprisingly, in its guidelines, ICMR says that,

> “Experimental xenotransplantation must only be permitted between animal species. Animal-to-man transplants must not be permitted at the present level of knowledge, which may be referred to the Central/ National Ethical Committee on Human Research”207.

We, however, will still engage with its patenting. If at all this technique is perfected and becomes acceptable, monopolisation thereof will be, we humbly submit, difficult due to several factors. Firstly, we consider GM-animals that become donors or sources of xeno-organs. Given the threshold bar on “plants and animals or any parts”208, patenting them, we opine, is impossible. Coming to surgeries to transplant such xeno-organs, they shall be again hit by ineligibility of “any process for the

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206 *Id. r. 29(2)*
207 *Supra 164 at 87*
208 *Supra 32*
medicinal, surgical, curative, prophylactic” ... “or other treatment of human beings or any similar process for a similar treatment of animals”\textsuperscript{209}. In this “public order or morality”\textsuperscript{210} will also constitute a barrier to the procedures or method of creating xenotransplants or of manufacturing suitable animals for the same. But there must be, for this last aspect, within IPO guidelines, or law, some specific exclusion. Interestingly in absence thereof, at IPO, following tabulated applications do exist. Each, however, is not yet granted.

**Table 4.1- Indian Xenograft Applications**\textsuperscript{211}

<table>
<thead>
<tr>
<th>S. No.</th>
<th>Application and Year</th>
<th>Title</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>“2338/CHE/2013”</td>
<td>“A procedure for fabricating xenograft using mammalian cholecyst derived extracellular matrix for wound healing applications”</td>
<td>“Published”</td>
</tr>
<tr>
<td></td>
<td>2013</td>
<td></td>
<td>Internal Status: Not mentioned</td>
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<tr>
<td>2.</td>
<td>“818/CHE/2009”</td>
<td>“An implantable xenograft prepared from a non human tissue portion”</td>
<td>“Published”</td>
</tr>
<tr>
<td></td>
<td>2009</td>
<td></td>
<td>FER date: 19/12/2016</td>
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<tr>
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<td>Internal Status:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>“Application is under”</td>
</tr>
</tbody>
</table>

\textsuperscript{209} *Id. s. 3(i), it says that “The following are not inventions within the meaning of this Act” ... “any process for the medicinal, surgical, curative, prophylactic [diagnostic, therapeutic] or other treatment of human beings or any process for similar treatment of animals to render them free of disease or to increase their economic value or that of their products”.*

\textsuperscript{210} *Id. s. 3(b)*

\textsuperscript{211} This information was obtained by using keyword “Xenograft” in “Title” column of online “inPASS” search facility of IPO. Information was sought over both “Published” and “Granted” applications. There are no granted patents. On keying in “Xenotransplantation” for either category, no results were obtained. In the table, “FER” refers to “First Examination Report” wherein objections-technical and substantive, are raised. Here, “CHE” means the Chennai Patent Office. The search facility can be accessed by following appropriate links at [www.ipindia.nic.in](http://www.ipindia.nic.in) (last visited on January 20, 2017)
Interestingly, the first application embraces “xenograft” taken “from gall bladder of any species” for use in “human or veterinary patients with any type of skin wound including chronic and acute wounds.” The second one covers “tissue heart valves” which literature suggests are non-controversial. The last application claiming only “method” has already languished for more than a decade. There must exist, we humbly opine, a clear policy or guidance for dealing with such afore-quoted innovations. Illustratively, the innovation in the first application noted here could actually be extremely controversial and it must be strictly assessed. IPO, we opine, should be circumspect and must, we humbly proffer, evolve some rule/policy for such innovations. This, thus, is our analysis of Xenotransplant monopolies.

Finally, while discussing, in this chapter, the bewildering bio-innovations, certain unmistakable aspects concerning their monopolisation were apparent. Illustratively, unlike, U.S. or EPO, Indian courts never, in bio-patents’ context, dealt or engaged with the elaborate, multitudinous, and polarised perspectives or arguments. Perhaps, Indian system grew, sans extensive judicial deliberations, largely because TRIPS got thrust upon it. Moreover, another glaring aspect is the discomfort, the uneasiness, the

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212 Application No. “2338/CHE/2013” Claim 3
213 Id. Claim 2
perpetual struggle of protecting, of bringing the bio-innovations within patent rubric’s fold. Illustratively, Canada rejected patents on so-called “higher life forms”, while EPO is undecided as regards products of “essentially biological processes”. Humans, though, remain sacrosanct. Interestingly, non-commodification or even non-alteration in context thereof, we saw, is attributable not to technological inability but to our ideal of dignity.